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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
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09/955,502

09/18/2001

Diana Downs

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12/19/2006

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EXAMINER

DUFFY, PATRICIA ANN

ART UNIT

PAPER NUMBER

1645

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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3 MONTHS

12/19/2006

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/955,502 | DOWNS ET AL. | |
| | Examiner | Art Unit | |
| | Patricia A. Duffy | 1645 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2005 and 19 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,16-19,21,23 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,16-19,21,23 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2006</u> . | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO AMENDMENT

The amendment and declaration filed 12-27-05 has been entered into the record. Claims 2-15, 20, 22, 24 and 26 have been cancelled. Claims 1, 16-19, 21, 23 and 25 are pending and under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Withdrawn

The rejection of claims 1, 16-19, 21, 23 and 25 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn based on Applicants amendments to the claims.

The rejection of claims 1, 16, 17, 18, 19, 21, 23 and 25 under 35 U.S.C. 102(b) as being anticipated by Gralnick et al (Abstracts of the General meeting of the American Society for Microbiology, 100p441, May 21-25, 2000) is withdrawn based on Applicants amendments to the claims.

The rejection of claims 1, 16, 17, 18, 19, 21, 23 and 25 under 35 U.S.C. 102(b) as being anticipated by Gifford et al (Journal of Bacteriology, 181(14):4223-4236, July 1999) is withdrawn based on Applicants' amendments to the claims.

Rejections Maintained

Claim 1, 16-19, 21, 23 and 25 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

had possession of the claimed invention is maintained for all the reasons made of record in prior office actions and herein. The remaining issues are set forth below.

As to claim 1, Applicants' arguments and amendment have been carefully considered, but the claims still recites "gene". This issue can be resolved by amending the claim to recite "...of a nucleic acid encoding the YggX polypeptide as set forth in SEQ ID NO:11".

Applicants argue that the claims as amended should not be limited to overexpression of endogenous YggX and submit a second declaration from Dr. Dianna Downs. Declarant provides evidence that the *E. coli* YggX homolog expressed in a *Salmonella* strain with the endogenous YggX inactivated provides for alleviation of superoxide-mediated damage of the *Salmonella* strain as measured by bacterial growth in a culture medium. While this provides evidence of heterologous alleviation by a closely related YggX homolog for the claimed "reducing superoxide damage to a bacteria cell", it does not support claims drawn to "increasing resistance of a bacterial enzyme having an oxygen labile Fe-S cluster/center to oxidative damage as recited in claims 19, 21, 23, 25 and does not provide evidence of such. Further, Declarant attests that the claimed homologs are 93% identical and the skilled artisan would accept functional equivalence as demonstrated by Pompiliello et al and Osborne et al. This is not persuasive because many of the homologs recited in the claims are not 93% identical as compared to SEQ ID NO:11 or any other sequence and neither of the relied upon references establish this fact. The consensus sequence of SEQ ID NO:1 does not set forth a sequence in which all members must be 93% identical. Further, the skilled artisan at the time of invention would not assume a functional assignment based on mere alleged similarity. Attwood et al (Science, 290:471-473, 20 October 2000) teach that "... it is presumptuous to make functional assignments merely on the basis of some degree of similarity between sequences (and it is not always clear what we mean by "function"); very few structures are known compared with the number of sequences, and structure prediction methods are unreliable (and knowing structure does not inherently tell us function);..." (see page 471, column 1, second full

paragraph). Further, Gifford et al of record (Journal of Bacteriology, 181(14):4223-4236, 1999) teaches that the YggX homologs are not 93% identical as compared to each other (see Figure 9B, page 4233). In fact, the only comparison of that is at least 93% identical is *Salmonella typhimurium* and *E. coli*. The structure and functional equivalence of the claimed YggX homolog polypeptides was not established in the art at the time of filing or in the specification and one skilled in the art would not readily appreciate such at the time of filing in view of Attwood discussed *supra*. As such, the declaration is insufficient to support claims 16 and 17 and cannot support claims 19, 21, 23 and 25 because it did not address activity or amount of oxidative damage of any bacterial enzyme having an oxygen labile Fe-S cluster/center.

The rejection is maintained.

Claims 1, 16-19, 21, 23 and 25 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained essentially for reasons made of record in the final rejection mailed 10-18-04, 6-29-05 and reasons made of record herein.

Applicants have amended the claims to recite comparison is to the same cell in the absence of vector based expression of the YggX gene (i.e. the parental cell). However, Applicants do not point to the specification by page and line number where support for this comparison can be found and a such does not resolve the issue of new matter. As previously set forth the basis for comparison of activity as claimed is relative to "any cell" not expressing the yggX gene/homolog. This is not supported by the specification as filed. The sole apparent support for this language is at [0058], "We observed no increased superoxide dismutase activity in *yggX** mutant extracts," and the basis for comparison is

not explicitly stated in the specification and is not stated relative to vector-based expression or co-expression or if this was observed in the genus. The yggX* mutant is not apparently generated using a vector-mediated expression system. It is unknown how the yggX* mutant was generated and what it was specifically compared to and the answer does not logically flow from the recited passage. There are at least two possibilities the *Salmonella typhimurium* wild type strain DM5104, or DM5647 where the yggX was disrupted (see page 5-6, description of Figure 2). There is no indication of which of these two, if either, was used for the comparison. With respect to increased resistance relative to cells in the absence of the vector-based expression of the yggX gene has no implicitly or explicit support in the specification as filed.

This issue is best resolved by Applicants pointing to the specification by page and line number where written description support can be found for these limitations.

New Rejections Based on Amendment

Claims 1, 16-19, 21, 23 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 1, the claim is indefinite because it recites the polypeptide as set forth in gene SEQ ID NO:11, however, SEQ ID NO:11 is a polypeptide not a gene. This issue is best resolved by deleting the word "gene".

As to claims 19, 21, 23 and 25, the claims are confusing in the recitation of "in the absence of vector based expression" because there is no vector based expression of the yggX polypeptide recited in the claim, therefore the claims appear to be missing a critical element or step such as vector-based expression.

The claims (1, 16-19, 21, 23 and 25) are also confusing because of multiple antecedent basis problems with recitation of "the cells" and it is unclear which cells are

being particularly being referenced, the bacterial cells of the preamble, the cells comprising the vector or some other cell.

Claims 1, 16, 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims now recite "examining the oxygen-labile enzyme". The specification provides written description of oxygen-labile proteins in the original claims, the specification discusses bacterial enzymes having an oxygen-labile Fe-S cluster/center. The new subgenus of oxygen labile enzymes lacks specific conception by way of written description at the time of filing. The application as filed conceives of a genus of oxygen labile proteins and a species of oxygen labile enzyme having a Fe-S oxygen labile center/cluster; but does not disclose the subgenus of oxygen labile enzymes as currently recited. It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. *In re Smith* 173 USPQ 679, 683 (CCPA 1972). See MPEP 2163.05(b). Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Status of Claims

All claims stand rejected.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

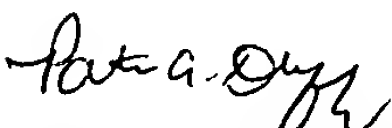
§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 6:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Jeffrey Siew can be reached on 571-272-0787.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Patricia A. Duffy

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Primary Examiner

Art Unit 1645